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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO..
10/807,897	03/24/2004	Rong Xiang	TSRI 874.1	6550

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EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,897	XIANG ET AL.	
	Examiner	Art Unit	
	Wu-Cheng Winston Shen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-50 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 (each in part), 4, 7-9, 16-19, and 20-25, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, having the amino acid residue sequences of **SEQ ID No: 2**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

II. Claims 1-3 (each in part), 5, 16-19, and 20-25, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, having the amino acid residue sequences of **SEQ ID No: 23**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

III. Claims 1-3 (each in part), 6, 16-19, and 20-25, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, having the amino acid residue sequences of **SEQ ID No: 24**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

IV. Claims 1, 10 (each in part), 11, 13-15 (each in part), 16-19, and 20-25, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, having the amino acid residue sequences of **SEQ ID No: 27**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

V. Claims 1, 10 (each in part), 12, and 13-15 (each in part), 16-19, and 20-25, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, having the amino acid residue sequences of **SEQ ID No: 29**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

VI. Claims 1, 26 (each in part), 27-29, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, encoded by polynucleotide sequences of **SEQ ID No: 1**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

VII. Claims 1, 26 (each in part), 27-29, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, encoded by polynucleotide sequences of **SEQ ID No: 3**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

VIII. Claims 1, 26 (each in part), 27-29, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, encoded by polynucleotide sequences of **SEQ ID No: 26**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

IX. Claims 1, 26 (each in part), 27-29, drawn to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, encoded by polynucleotide sequences of **SEQ ID No: 28**, and at least one immunoactive gene product in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

X. Claims 30-38, and 42-50, drawn to a method of inhibiting tumor growth in a mammal and a method of vaccinating a mammal against cancer, the said methods comprise the step of administering to the mammal an effective immunological response eliciting amount of a DNA vaccine comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product in a pharmaceutically acceptable carrier, whereby said mammal exhibits an immune response elicited by vaccine and specific to tumor cells, classified in class 514, subclass 44.

XI. Claims 39-41, drawn to a transformed host cell transfected with a vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product, an isolated plasmid vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein, and an article of manufacture comprising a

DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product, classified in 435, subclass 252.3.

Inventions of the Groups I - XI are patentably distinct, each from the other. Inventions are patentably distinct if it can be shown that they are not disclosed as capably of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, Groups I-V are directed to a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, having the amino acid residue sequences of SEQ ID No: 2 (Group I), SEQ ID No: 23 (Group II), SEQ ID No: 24 (Group III), SEQ ID No: 27 (Group IV), and SEQ ID No: 29 (Group V), and at least one immunoactive gene product in a pharmaceutically acceptable carrier.

Groups VI-IX are directed a DNA vaccine suitable for eliciting an immune response against cancer comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family) protein, encoded by polynucleotide sequences of SEQ ID No: 1 (Group VI), SEQ ID No: 3 (Group VII), SEQ ID No: 26 (Group VIII), and SEQ ID No: 28 (Group IX), and at least one immunoactive gene product in a pharmaceutically acceptable carrier.

Group I-IX are distinct one from each other because structurally distinct nucleotide/amino acid sequences are distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct

inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide/amino acid sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

Group X is directed to drawn to a method of inhibiting tumor growth in a mammal and a method of vaccinating a mammal against cancer, the said methods comprise the step of administering to the mammal an effective immunological response eliciting amount of a DNA vaccine comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product in a pharmaceutically acceptable carrier, whereby said mammal exhibits an immune response elicited by vaccine and specific to tumor cells.

Group XI is directed to a transformed host cell transfected with a vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product, an isolated plasmid vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein, and an article of manufacture comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product.

Groups I-IX are distinct from Group X because Group I-IX is directed to a DNA vaccine whereas Group X is directed a method of inhibiting tumor growth in a mammal and a method of vaccinating a mammal against cancer. The sequences of DNA vaccine of Groups I-IX are not obvious over the steps of the method of Group X.

Groups I-IX are distinct from Group XI because Group I-IX is directed to a DNA vaccine whereas Group XI is directed a transformed host cell transfected with a vector, an isolated plasmid vector, and an article of manufacture comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product. The sequences of DNA vaccine of Groups I-IX are not obvious over the compositions of an article, an isolated plasmid vector, and a transformed host cell of Group XI.

Group X is distinct from Group XI because Group X is directed a method of inhibiting tumor growth in a mammal and a method of vaccinating a mammal against cancer whereas Group XI is directed to a transformed host cell transfected with a vector, an isolated plasmid vector, and an article of manufacture comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product. The step of the method of Group X is not obvious over the compositions of an article, an isolated plasmid vector, and a transformed host cell of Group XI.

The search for claims in Group I-XI is distinct one from each other and not co-extensive and thereby presents search burdens on the examiner.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Additionally, for the same reason as stated above regarding the distinction between Group I-IX, claim **28** of each Group VI-IX named above is subject to further restriction. Applicant is required to further elect a specific polynucleotide sequence SEQ ID NO from the claim 28. This is **NOT** an election of species. Structurally distinct nucleotide sequences are distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

Additionally, claims **16, 32, 44** of each Group I-V and X named above are subject to further restriction. Applicant is required to further elect a cytokine or a ligand for a natural killer

cell surface receptor. This is **NOT** an election of species. A cytokine is patentably distinct from a ligand for a natural killer cell surface receptor for the reasons stated above and for their distinct structures and functions.

5. The following election of species is required under 35 U.S.C. 121:

(i) This application contains claims directed to the following patentably distinct species: surviving protein and livin protein in claims **2, 31, 43**. The species are independent or distinct because they are different protein with distinct structures and functions.

(ii) This application contains claims directed to the following patentably distinct species: a chemokine, a hematopoietin, an interferon, a natural killer cell stimulatory factor, and a cytokine production-inducing factor in claim **17**. The species are independent or distinct because they are because they are different cytokine with distinct structures and functions.

(iii). This application contains claims directed to the following patentably distinct species: human MICA, human MICB, human ULBP1, human ULBP2, and human ULBP3 in claim **19**. The species are independent or distinct because they are different ligand for a natural killer cell surface receptor with distinct structures and functions.

(iv). This application contains claims directed to the following patentably distinct species: attenuated *Salmonella typhimurium*, *Salmonella typhi, Shigella* species, *Bacillus* species, *Lactobacillus* species, *BCG, Escherichia coli, Vibrio cholerae, Campylobacter* species, *and Listeria* species in claims **22, 35, 47**. The species are independent or distinct because they are different attenuated bacteria vector with distinct characteristics with regard to their structures and immune responses elicited.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **2, 31, 43**; **17; 19;** and **22, 35, 47** are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. It is required to be consistent between election of an invention and election of species regarding a polynucleotide and its corresponding encoded amino acid sequences.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Ram Shukla, can be reached on (571) 272-0735. The fax number for TC 1600 is (571) 273-8300. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Wu-Cheng Winston Shen

Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER